Safe Chain Solutions 822 Chesapeake Drive Cambridge, MD 21613

Title:	**Standard Operating Procedures for Suspect & Illegitimate Product**
Issue Date:	**5/2/2015**
Effective Date:	**5/9/2015**

PURPOSE:

This policy will serve as a guideline to ensure no illegitimate products enter the drug supply chain.

INSTRUCTIONS:

Each Safe Chain Solutions employee should have a clear understanding of the proper way to verify a product's legitimacy and the correct handling of suspect products.

DEFINITIONS:

1. Illegitimate product means a product for which credible evidence shows that the product:
    - is counterfeit, diverted, or stolen;
    - is intentionally adulterated such that the product would result in serious adverse health consequences or death to humans
    - is the subject of a fraudulent transaction
    - appears otherwise unfit for distribution such that the product would be reasonably likely to result in serious adverse health consequences or death to humans.
2. Suspect Products are defined by Section 581 (21) of the FD&C Act as products that are:
    - Potentially counterfeit, diverted, or stolen;
    - Potentially intentionally adulterated such that a the product would result in serious adverse health consequences or death to humans;
    - Potentially the subject of a fraudulent transaction; or
    - Appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans.

PROCEDURES:

1. Process to identify suspect products in a timely and efficient manner. This is directly referenced from DSCSA Implementation: Identification.
    a. New Trading Partner set up
        i. Purchasing from a new trading partner
        ii. Receiving unsolicited sales
        iii. Purchasing products online from an unknown source
        iv. Purchasing a product from a source that that is known or suspected to have been involved in transactions of suspect products such as:
            - A trading partner that has bene involved in business transactions where thy have sold or delivered suspect or illegitimate products.
            - A trading partner that has a history of problematic or potentially false transaction histories or pedigrees, such as those that contain misspelled words or incomplete information.

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- A trading partner that is reluctant to provide a transaction history or pedigree associated with the product being purchased, or does not do so in a timely manner.
- Transaction information, a transaction statement, and/or transaction history that appears to be incomplete or suspicious.

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b. Supply, Demand, History, and Value of the Product

• Product that is generally in high demand in the U.S. market.

• Product that is in higher demand because of its potential or perceived relationship to a public health or other emergency (e.g., antiviral drugs).

• Product that has a high sales volume or price in the United States.

• Product that has been previously or is currently being counterfeited or diverted (e.g., HIV, antipsychotic, or cancer drugs).

• Product that has been previously or is currently the subject of a drug shortage

(see a list of current drugs in shortage at (http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/Shortages/default.htm and http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050792.htm for more information).

• Product that has been or is the subject of an illegitimate product notification under the DSCSA or other alert or announcement related to drug quality.

• Product that has been or is the subject of an FDA counterfeit or cargo theft alert.

c. Appearance of the Product

• Appearance of a package or a container used for transport (e.g., case or tote) that seems suspicious (e.g., it has a label that contains misspellings or appears different from the standard label for that product in color, font, images, or otherwise).

• Package that uses foreign terms, such as a different drug identification number rather than the National Drug Code (NDC).

• Package that is missing information, such as the lot number or other lot identification, or the expiration date.

• Package that is missing anti-counterfeiting technologies normally feature on the FDA-approved product that are easily visible to the eye, such as holograms, color 206 shifting inks, or watermarks.

• Finished dosage form that seems suspicious (e.g., it has a different shape or color 209 from the FDA-approved product, a different or unusual imprint, an unusual odor, 210 or there are signs of poor quality like chips or cracks in tablet coatings or smeared 211 or unclear ink imprints).

2. Recommendations on How Trading Partners Might Identify Suspect Product and Determine Whether the Product Is a Suspect Product as Soon as Practicable

• Be alert for offers of product for sale at a very low price or one that is "too good to be true."

• Closely examine the package and the transport container (such as the case or tote):

- To look for signs that it has been compromised (e.g., opened, broken seal, damaged, repaired, or altered).

- To see if it has changed since it was last received for an unexplained reason (e.g., a notification about the change from the manufacturer has not been received).

- To see if product inserts are missing or do not correspond to the product.

- For shipping addresses, postmarks, or other materials indicating that the product came from an unexpected foreign entity or source.

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• Closely examine the label on the package, or the label on the individual retail unit, if applicable, for:

- Any missing information, such as the lot number or other lot identification, NDC, or strength of the drug.
- Any altered product information, such as smudged print or print that is very difficult to read.
- Misspelled words.
- Bubbling in the surface of a label.
- Lack of an Rx symbol.
- Foreign language with little or no English provided.
- Foreign language that is used to describe the lot number.
- A product name that differs from the name of the FDA-approved drug.
- A product name that is the product name for a foreign version of the drug.
- A product that is transported in a case or tote, when not expected under the circumstances.
- Lot numbers and expiration dates on product that do not match the lot numbers and expiration dates of its outer container.

3. Protecting the Supply Chain

a. The Compliance Department will be responsible for maintaining up to date records that verify trading partners are in compliance with licensing and reporting requirements. The trading partners will be required to submit proof of licensure and reporting as deemed necessary. If any of the above referenced indicators appear during a transaction the product will be moved to quarantine and the FDA will be notified within 24 hours.

b. Investigations of suspicious products should be a priority and should be initiated and concluded in a reasonable timeframe. Employees will be responsible for notifying management who will then notify the FDA using the following link: http://www.accessdata.fda.gov/scripts/cder/email/drugnotification.cfm

c. Products awaiting verification must be quarantined immediately and remain in the quarantine area until the conclusion of the investigation. Trading partners should be notified and transaction history and transaction information should be verified.

d. In the event that a suspect product is determined to be a legitimate, management will notify the FDA immediately so the product can be cleared for distribution. All records pertaining to suspect transaction are to be stored for a minimum of 6 years.

4. Handling of illegitimate products

a. The definition of an illegitimate product according to Section 581 (8) of the FD&C Act is credible evidence showing:

- Counterfeit, diverted, stolen;
- Is intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;
- Is the subject of a fraudulent transaction; or
- Appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans.

b. Safe Chain Solutions Management will be responsible for initiating communication with the manufacturer of a suspect product. The manufacturer will be responsible for providing evidence of legitimacy to Safe Chain for review. If the product is determined to be illegitimate the following process will occur:

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Quarantine the suspect product within Safe Chain's possession and stored away from products to be distributed until disposition.

- Management will be responsible for the disposition of all illegitimate products. A disposal request will be submitted to our return distributor and the illegitimate product will be destroyed.
- Safe Chain Solutions will provide assistance to other trading partners to disposition illegitimate products by following the same procedure listed above in the event it is appropriate to accept a return.
- Safe Chain Solutions will keep illegitimate products at the request of the FDA or manufacturer for analysis. If Safe Chain does not receive a request all of the illegitimate products will be dispositioned for destruction.

c. Once a product has been determined to be illegitimate Management will complete Form FDA 3911 and notify trading partners within 24 hours. Only trading partners who are suspected to have received the illegitimate product will be notified.

d. Any illegitimate products received after the initiation of Form 3911 must be identified upon receipt.

5. Termination of Illegitimate Product Notification

a. Safe Chain Solutions and the FDA may determine the illegitimate product notification is no longer necessary. In this event, FDA Form 3911 will be updated to reflect reasoning for termination. All trading partners who received notification will be informed of the termination as well. The records of the illegitimate product notification and outcome will be stored for a minimum of 6 years.